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| APPLICATION NO.         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 08/896,821              | 07/18/1997  | STEVEN C. QUAY       | SNUS125             | 3671             |
| 36335                   | 7590        | 11/24/2003           | EXAMINER            |                  |
|                         |             |                      | HARTLEY, MICHAEL G  |                  |
|                         |             | ART UNIT             |                     | PAPER NUMBER     |
|                         |             | 1616                 |                     |                  |
| DATE MAILED: 11/24/2003 |             |                      |                     |                  |

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                    |                 |
|------------------------------|--------------------|-----------------|
| <b>Office Action Summary</b> | Application No.    | Applicant(s)    |
|                              | 08/896,821         | QUAY, STEVEN C. |
|                              | Examiner           | Art Unit        |
|                              | Michael G. Hartley | 1616            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 08 August 2001.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 15,19-25,30,36 and 37 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 15 and 19 is/are allowed.
- 6) Claim(s) 19-21,23-25,36 and 37 is/are rejected.
- 7) Claim(s) 22 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

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***Response to Amendment***

The amendment filed 8/8/2001 has been entered. Claims 16-18, 26-29 and 31-35 have been canceled. Consequently, claims 15, 19-25, 30, 36 and 37 are pending and have been examined herein. Note: the previously withdrawn claims have been rejoined herein and examined in accordance with Markush practice, as no prior art was found to reject the elected species.

***Response to Arguments***

Any previous rejections that are not reiterated herein have been withdrawn.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20, 24 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,620,404. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20 and 30 are generic to all that is recited in claim 1 of the patent. That is, claims 20 and 30 fall entirely within the scope of claim 1 of the patent, or in other words, these claims are anticipated by claim 1 of the patent. Claim 1 of the patent limits the gas to perfluoropropane or perfluoropentane or mixtures thereof, and these gases are recited as the gas species in the claimed method.

Claims 20, 24, 25 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20, 25

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and 30 are generic to all that is recited in claim 1 of the patent. That is, claims 20, 25 and 30 fall entirely within the scope of claim 1 of the patent, or in other words, these claims are anticipated by the claims of the patent. Claim 1 of the patent limits the gas to perfluoropropane, perfluorobutane and perfluorobutane which are the same gases as claimed and limits the microbubbles to free microbubbles which are encompassed by methods of using the microbubbles for ultrasound as claimed.

Claims 20, 21, 23, 24, 25, 30, 36 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 and 1-17 of U.S. Patent No. 5,558,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20, 25 and 30 are generic to all that is recited in claim 19 of the patent. That is, claims 20, 25 and 30 fall entirely within the scope of claim 19 of the patent, or in other words, these claims are anticipated by the claims of the patent. Claim 19 of the patent limits the gas to perfluoropropane, perfluorobutane and perfluorobutane, which are the same gases as claimed and limits the microbubbles to liquid in liquid colloidal dispersion, and allowing microbubbles to form. The compositions to be used in the patented method claim are shown by claims 1-17, which include protein solutions, etc. The instant claims only state that microbubbles are to be used, thus are encompassed by methods as claimed.

Claims 20, 24, 25 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,558,094. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20, 25 and 30 are generic to all that is recited in the claims of the patent. That is, claims 20, 25 and 30 fall entirely within the scope of the claims of the patent, or in other words, these claims are anticipated by the claims of the patent. Claim 1 limits the gas to having a specific Q value; however, these are the same gases as claimed, as can be seen by the dependent claims of the patent, which recite the same gas species'. Also, the patent claims recite free gas microbubbles that are within the scope of microbubbles (generic) as claimed.

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Claims 20, 24, 25 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,393,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20, 25 and 30 are generic to all that is recited in the claims of the patent. That is, claims 20, 25 and 30 fall entirely within the scope of the claims of the patent, or in other words, these claims are anticipated by the claims of the patent. Claim 1 limits the gas to having a specific Q value; however, these are the same gases as claimed, as can be seen by the dependent claims of the patent, which recite the same gas species'. Also, the patent claims recite free gas microbubbles that are within the scope of microbubbles (generic) as claimed.

Claims 20, 21, 23-25, 30, 36 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-56 of copending Application No. 08/466,104. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20, 25 and 30 are generic to all that is recited in claim 48, 51 and 54 of the copending application. That is, claims 20, 25 and 30 fall entirely within the scope of claims 48, 51 and 54 of the copending application, or in other words, the claims are anticipated thereby. For example, the claims of the co-pending application '104 are a method wherein the contrast agent requires a protein for stabilization, while the instant claims are generic thereto. However, such protein compositions are included as shown by, for example, claims 36 and 37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**NOTE:** Applicant has acknowledged their intention to file terminal disclaimers to overcome most of the obviousness type double patenting rejection set forth above. An updated search uncovered two additional double patenting rejections that have not been addressed in the response, and are included hereinabove. The terminal disclaimers should include disclaimers for these additional rejections.

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***Allowable Subject Matter***

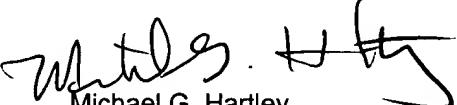
Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15 and 19 are allowed. The prior art fails to teach or suggest the method using microbubbles of a gas including perfluorohexane in ultrasound imaging as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
11/14/2003